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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,995	01/13/2004	Peter M. Bonutti	780-A03-021-4	1470

33771 7590 05/26/2005

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EXAMINER

REIP, DAVID OWEN

ART UNIT PAPER NUMBER

3731

DATE MAILED: 05/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/755,995

Applicant(s)

BONUTTI, PETER M.

Examiner

David O. Reip

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 30-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/13/04, 5/5/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Species 3 in the reply filed on 4/13/05 is acknowledged. The traversal is on the ground(s) that the examiner has not provided a prima facie showing of a serious burden by showing appropriate explanation of separate classification, or separate status in the art, or a different field of search. This is not found persuasive because there is no disclosure of relationship between species (see MPEP 806.04(b)). Therefore, the species are independent inventions and it is not necessary to show a separate status in the art or separate classification (see MPEP 808.01(a)).

The requirement is still deemed proper and is therefore made FINAL.

Claims 27-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/13/05.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims

are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 41 (second occurrence) been renumbered 42.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10-13, 22-26, 30-33, and 40-42 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Michelson (U.S. Pat. No. 5,609,635). Michelson clearly shows an implantable device “for changing the special relationship between first and second bones” (note col.6, lines 29-33, “The angular relationship of the upper and lower surfaces 112 and 114 places and maintains the vertebrae adjacent to those surfaces in an angular relationship, *creating* and maintaining the desired lordosis of the spine”). Further, see col. 6, second full paragraph, for disclosure to BMP as well as other fusion enhancing materials. See the embodiments of Figs. 9-16 showing porous material. See the embodiment of Fig. 31 showing “fastener means” 708 and screw 718.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-9, 14-21, and 34-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson in view of Jefferies (U.S. Pat. No. 4,394,370). In col. 6, Michelson discloses that the internal chamber of the implant "can be filled and hold any natural or artificial osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material," and then recites some specific examples, including "bone harvested from the patient, or bone growth inducing material such as, but not limited to, hydroxyapatite, hydroxyapatite tricalcium phosphate, or bone morphogenic protein. The implant 100 itself is made of material appropriate for human implantation, such as titanium and/or may be made of, and/or filled and/or coated with a bone ingrowth inducing material such as, but not limited to, hydroxyapatite or hydroxyapatite tricalcium phosphate or any other osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material." However, Michelson does not specifically disclose demineralized bone powder and collagen. Jefferies teaches both demineralized bone powder and collagen as bone graft material. Therefore, it would have been obvious to one of

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ordinary skill in the art at the time the invention was made to include demineralized bone powder and collagen as suitable substances for use in and/or on the Michelson implant, since those substances are well-known and are in common use in the art of bone fusion.

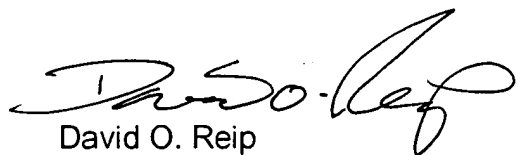
The courts have concluded that there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. In re McLaughlin, 170 USPQ 209 (CCPA 1971). Also, references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. In re Bozek, 163 USPQ 545 (CCPA 1969).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David O. Reip whose telephone number is 571-272-4702. The examiner can normally be reached on 7 A.M.- 4 P.M. Mon-Thu and every other Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "David O. Reip", is positioned above the printed name.

David O. Reip
Primary Examiner
AU 3731